PREGNANCY OUTCOMES IN SANTA CLARA COUNTY

1980 - 1985

SUMMARIES OF REPORTS OF TWO EPIDEMIOLOGICAL STUDIES

AND

TWO EXPOSURE ASSESSMENTS

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Summary of Reports of Two Epidemiological Studies and Two Exposure Assessments

Major Points

1. The census tract adjacent to Los Paseos, in which Well #13 is located, was more likely to receive water from Well #13 than the Los Paseos area in which a cluster of adverse pregnancy outcomes had been previously documented.

2. Rates of miscarriage and birth defects in this tract (5120.11) were not elevated during 1980-81 when the Los Paseos cluster was seen.

3. Rates of miscarriage and birth defects in both census tracts as well as in the comparison tracts were normal in 1982-1985.

Background

This report presents the results of two epidemiological studies of pregnancy outcomes and two related exposure assessments. These were conducted by the Epidemiological Studies and Surveillance Section of the California Department of Health Services (CDHS) with the cooperation of its contractor, the California Public Health Foundation, and the Santa Clara County Health Department. These studies were conducted to follow-up on two studies released by CDHS in January, 1985.

In the previously released studies, the Department reported a doubled rate of spontaneous abortions and tripled rate of birth defects in women who resided in a census tract (Los Paseos) which received drinking water from a well which had been contaminated by leakage of solvents from an underground storage tank operated by the Fairchild Semiconductor Company in South San Jose. At the same time, the Department documented a 2.2-fold increased rate of major cardiac malformations among the children of women residing in the seven-census tract area through which the contaminated water was distributed. The first of these studies ruled out confounding as the cause of these findings, and for both the role of the leak in causing these excesses was uncertain. Therefore, the Department conducted two epidemiological studies and two exposure assessments to follow-up on these results.

Methods

The first study in this report, the Pregnancy Outcome Follow-up Study (POFS), is similar in design to the first interview study. However, in POFS, women in a census tract adjacent to Los Paseos which was thought to also have been exposed to water from the contaminated well were interviewed about their pregnancies in 1980-81, in addition to re-interviewing the women in Los Paseos. Furthermore, this study looked at pregnancies in 1982-85 as well, so that the effect of closing the contaminated well could be analyzed. The study areas are shown in the attached map (Figure 1.1) and the design of these studies is shown schematically in Figure 1.2). (In a companion report on water exposure and pregnancy outcome released concurrently by the Department, this study is referred to as Fairchild II).

The 1985 Cardiac study was based on hospital data only and no interviews were conducted. In the Cardiac Study: Follow-up Cluster Investigation, cases and normal controls were interviewed in order to obtain more detailed information on exposure to water, to rule out confounding as an explanation for the observed association, and to look at the prevalence of cardiac defects in more recent births.

The 1985 studies contained limited information about the level and extent of the water contamination. In order to obtain more precise exposure information, hydrogeologic modelling of water flow within the distribution system of the water company which had operated the contaminated well was conducted. This is the subject of The Great Oaks Water Distribution Study.

Following the discovery of the leak, the Fairchild company prepared a materials balance report at the request of the Regional Water Quality Control Board. This report indicated no appreciable leakage from the failed tank before late May 1980. Because of the importance of the timing of the leak in interpreting the excesses documented in the epidemiological studies, the Department conducted a reanalysis of the Fairchild report. This is the Material Mass Balance Analysis.

Results

1. POFS

For the 1105 women with eligible pregnancies, 103 spontaneous abortions were available for analysis. The spontaneous abortion rate in the new exposed area in 1980-81 was only 4.7%, considerably lower than the overall rate of 9.9%. The odds ratio for comparing Los Paseos to its control tract in 1980-81 (OR=3.5), was similar to that seen in the original study (OR=2.4). No elevated rates were seen in 1982-85 for either the exposed areas (10.8%) or the control areas (10.6%). Odds ratios comparing the exposed and control tracts are shown in Figure 1.3. These results were substantially unchanged after controlling for other risk factors such as smoking, alcohol, medications, occupations etc.

A total of 37 birth defects were available for analysis. As in the prior study, an unusually high prevalence of birth defects (10.4%) was seen in the original exposed tract for 1980-81, but the prevalence in the new exposed tract was low during the same time period (1.9%). After 1982, frequence of birth defects in the exposed and control areas were similar (2.9% and 1.9%) and consistent with the prevalence reported by CBDMP for the five Bay Area counties (2.5%). Odds ratios for reportable birth defects are shown in Figure 1.4 by study year.

The frequency of low birth weight was also examined. The original study had reported a significant absence of low birth weight babies in the exposed area. In this study there was little difference seen between exposed and control areas in 1980-81 (2.4% and 2.6%) or during 1982-85 (3.8% and 4.0%).

Hydrogeologic modelling was conducted to estimate the flow of water from Well #13 throughout the Great Oaks Water Company distribution system and the levels of TCA women were likely to have received during their pregnancy based on their address and dates. Modelling was not carried out for 1980 pregnancies because the engineer who conducted this analysis concluded that it was unlikely that homes received any significant exposure to TCA before January 1981. This study finds that the new exposed tract had a considerably higher likelihood of exposure to water from Well #13 during 1981 (60%-100%) than the Los Paseos area (20%-60%) (Figure 1.7). Thus, the low spontaneous abortion rate in the new exposed tract in 1981 is inconsistent with the assumption that water from Well #13 was associated with high rates.

2. Cardiac study

For births in the comparison time period corresponding to exposure after the well was closed (9/1/82-12/31/83), there were three cases born in the study area, which was slightly less than expected. In the study area the prevalence was 1.7 per 1000 compared to 3.2 in the remainder of the county.

Overall, 106 mothers of cases born in the study period and 114 control mothers were interviewed. After correcting for address (when the first trimester address assigned a different exposure than the birth address) or water use (when woman drank no tap water), the odds ratio was very similar to that seen in the original study; the original study had presented a relative risk of 2.2, while this follow-up study found an odds ratio of 2.3 after these adjustments for misclassification.

The odds ratio for residence in the study area was statistically significant (95% CI, 1.2, 3.9), although the 95% confidence interval for the odds ratio in the follow-up study included 1.0 (95% CI, 0.61, 8.4). Adjustment for potential confounders had little effect on these estimates.

This study also examined the temporal distribution of cases throughout the study period. From the beginning of 1982 until the end of the study period (September 1982), seven cases would be expected, if the excess prevalence seen in 1981 in the study area continued at the same level until the well was closed. However, only two cases were seen. This deficit of cases in January-September 1982 is statistically significant (p=.03).

3. The Great Oaks Water Distribution Study

The Great Oaks Water Distribution Study showed that the distribution of water from Well #13 was very non-uniform across the seven census tracts that make up the Great Oaks Water Company service area. The distribution patterns changed somewhat from month to month, but not a great deal. Similarly there was little variation across nodes within a census tract. Ranges of the mean proportion of water from Well #13 received in each census tract are shown in Figure 1.7. As can be seen, the census tract originally considered exposed to Well #13 (Los Paseos) was less exposed than the adjacent tract which was considered as the new exposed area in POFS.

The results on the timing of the leak are less certain, but none of the scenarios considered would predict that the contamination reached Well #13 in any appreciable amounts before January of 1981.

4. Material Mass Balance Analysis

The Materials Balance Analysis did not identify sufficient documentation to provide an accurate estimate of the onset of the underground tank leak at Fairchild. Nevertheless, the review did not identify any data which would appreciably alter the estimate of May 1980 which was contained in the original Materials Balance Report. An initial leak at this time would be consistent with the estimates obtained in the Great Oaks Water Distribution Study. The Department found that the components used to solve the imbalance equation, such as solvents purchased, evaporated or hauled, must be considered unreliable and the extent of solvents lost remains uncertain.

Discussion

These studies represent an unprecedented effort on the part of the CDHS to conduct a cluster investigation. Together with the original Fairchild studies released in January 1985, they have required six years and over one million dollars to conduct. They have also required the patience and participation of the citizens of four census tracts who have cooperated during these years. The weight of the evidence is against the leak from the Fairchild plant as a cause of the original cluster. Nevertheless, there is little doubt that a cluster did occur, and its cause will probably never be known with certainty. Continued work by the Department on prenatal exposures may shed light on causes of this and other clusters in the future.

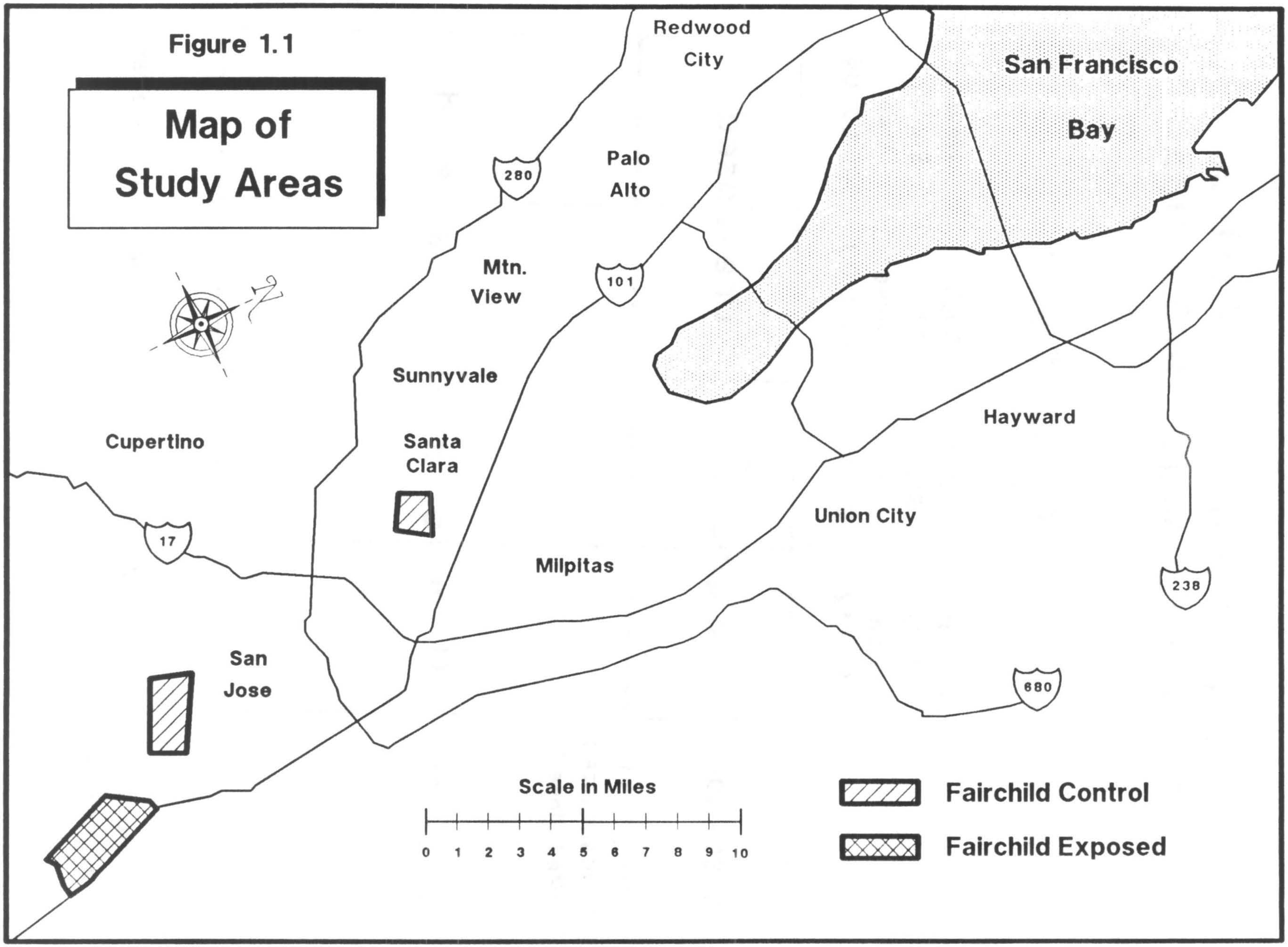


Figure 1.1

Map of Study Areas

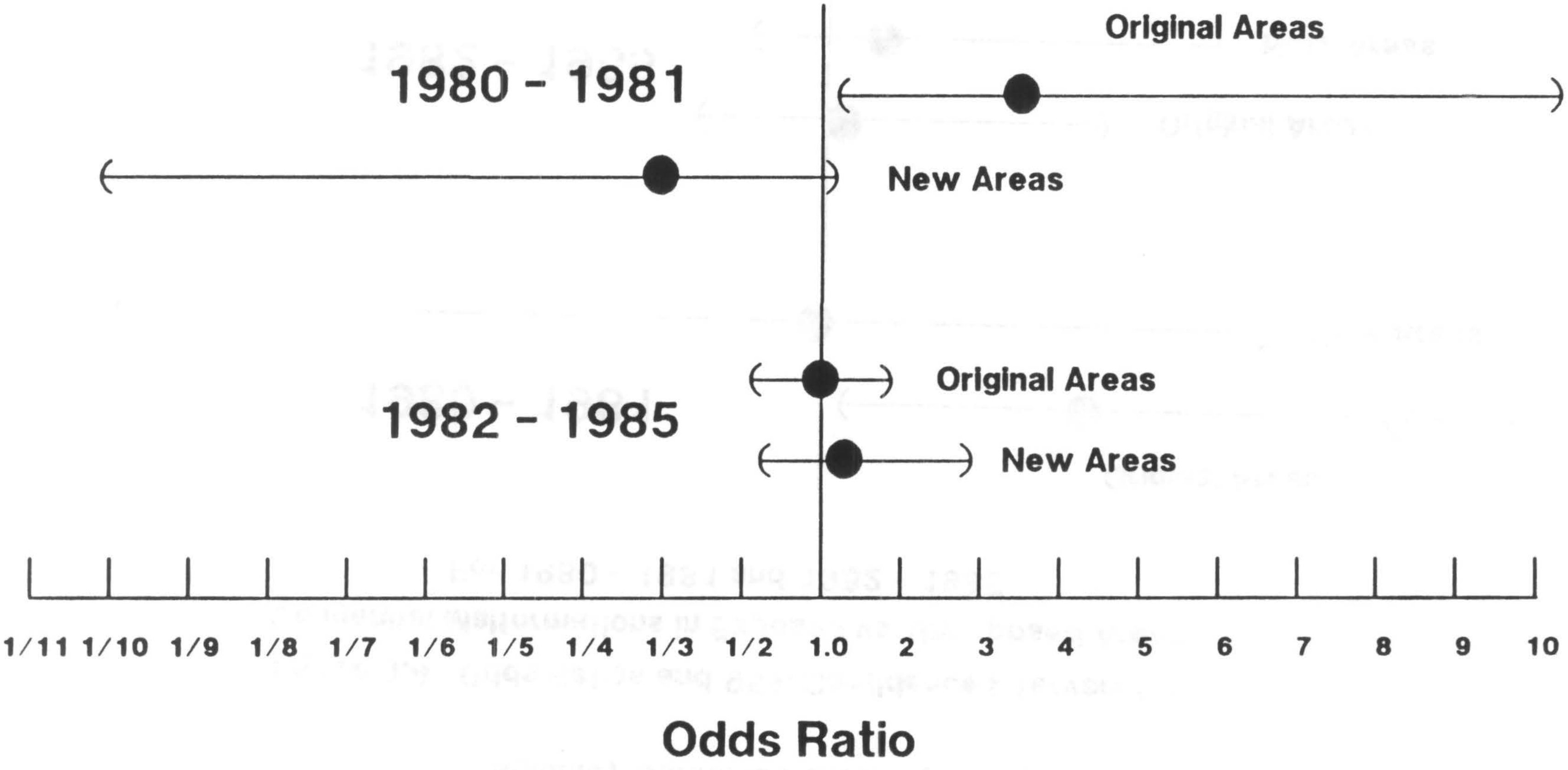
Figure 1.2 Four Census Tracts in Santa Clara County 1980 - 1985

	Census Tracts			
	Original Study Area 5120.12	New Study Area 5120.11	Original Study Area 5120.08	New Study Area 5053.0204
1980 - 1981	Exposed*		Unexposed	
Dec. 1981 Contaminated Well Closed				
1982 - 1985	Unexposed			

* Exposure to water contaminated by a leaking chemical waste tank at the Fairchild Camera Company.

Pregnancy Outcome Follow-Up Study

Figure 1.3 Odds Ratios and 95% Confidence Intervals for Spontaneous Abortions in Exposed vs. Unexposed Areas For 1980 - 1981 and 1982 - 1985



Pregnancy Outcome Follow-Up Study

Figure 1.4 Odds Ratios and 95% Confidence Intervals for Congenital Malformations in Exposed vs. Unexposed Areas For 1980 - 1981 and 1982 - 1985

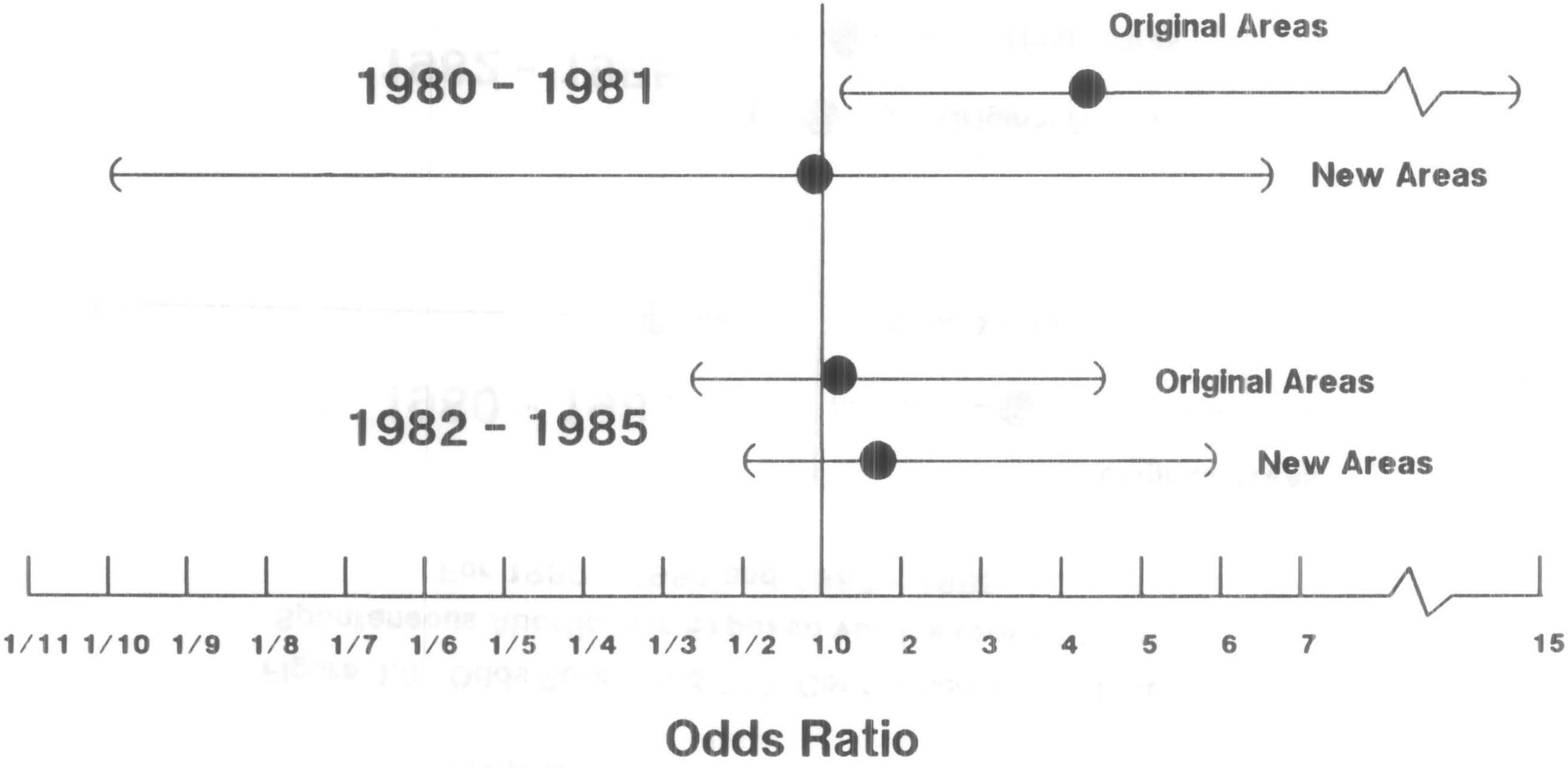
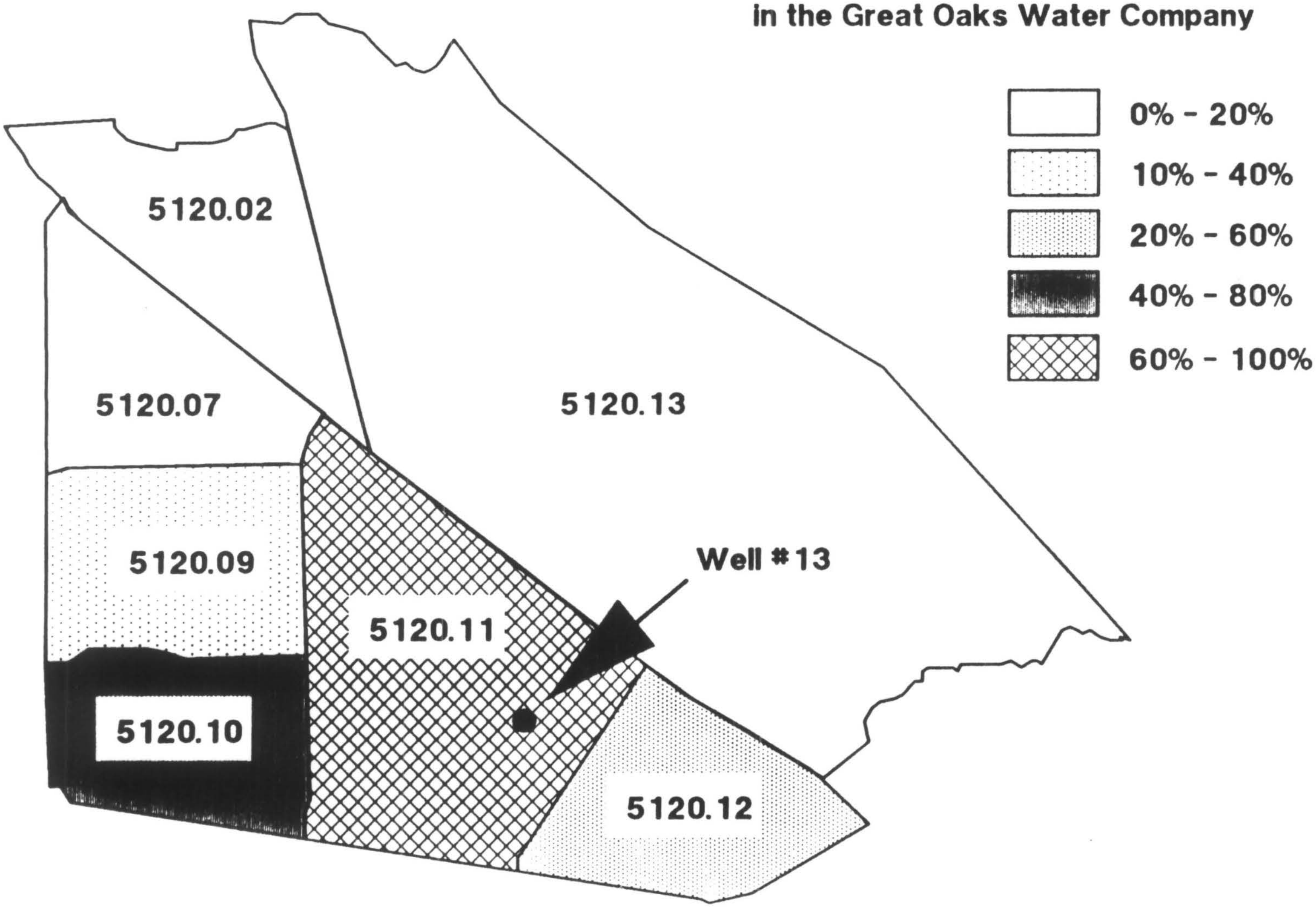


Figure 1.7

Estimated Percent of Water from Well #13 in 1981 for Census Tracts in the Great Oaks Water Company



PREGNANCY OUTCOMES IN SANTA CLARA COUNTY (1980-85)

Questions and Answers for the Community

On May 23, 1988, the California Department of Health Services, in collaboration with its contractor, the California Public Health Foundation, and with the cooperation of the Santa Clara County Health Department, released two interview studies on pregnancy outcomes in four census tracts in Santa Clara County. At the same time, the Department presented the results of two related exposure assessment studies. These questions and answers attempt to address the most likely concerns of the community regarding these studies.

Copies of the full report are available at local libraries. The report may be purchased at local Copy Mat stores throughout Santa Clara County. To obtain the location of the library and Copy Mat nearest you, or to obtain information about the study, call 415-540-2828.

Questions concerning the Pregnancy Outcome Follow-up Study

Q1. Why was the Pregnancy Outcome Follow-up Study conducted?

A. In 1981, residents of the Los Paseos area of South San Jose noticed an excess number of miscarriages and birth defects in their neighborhood. This concern arose at about the same time as a report that a nearby underground storage tank, operated by Fairchild Semiconductor Company, had leaked chemicals into a well which supplied drinking water to this neighborhood. The residents wondered whether the contaminated water was responsible for the miscarriages and birth defects. The Department of Health Services responded by conducting two studies to address the residents' concern. These were released in January 1985. One of these, the Pregnancy Outcome Study, documented the residents' suspicion that rates of miscarriage and birth defects were elevated in Los Paseos. However, the study did not conclude that the contaminated water had been responsible, and uncertainty about the cause of the excess remained. Furthermore, this study had no information about rates of miscarriage and birth defects after the contaminated well was removed from service in December 1981.

The Pregnancy Outcome Follow-up Study (POFS) repeated the original study with two important differences. It studied pregnancies in the census tract adjacent to Los Paseos, which was close to the contaminated well, in addition to restudying Los Paseos. Furthermore, it obtained data on pregnancies which occurred after the well was closed. Since it studied pregnancies through 1980-1985 it could compare pregnancies which occurred before and after the contaminated well was removed from service in 1981. For comparison purposes both studies also interviewed women in comparable control areas who received water from different water companies.

In summary, this study looked to see whether there were excesses of miscarriages or birth defects in both the Los Paseos area and the adjacent exposed tract in 1980-81. It also looked to see what happened to rates of miscarriages and birth defects after the well was closed.

Q2. Was the contamination from Well #13 responsible for the excess of miscarriages and birth defects found in the Los Paseos area in 1980-81?

A. Probably not. There were no excesses of miscarriages or of birth defects in the new exposed census tract during 1980 and 1981. If anything, there was a deficit of these conditions. The Department also used hydrogeologic methods to estimate the exposure to the contaminated water for each woman who was pregnant in 1981 and who lived in the exposed census tracts. If the contamination was the cause of adverse pregnancy outcomes, we would expect greater exposure to contaminated water among women with miscarriages and birth defects than among women with normal live births. This was not the case. There was no difference in the likelihood of receiving contaminated water between women with normal outcomes and adverse outcomes.

Q3. If the Fairchild leak was not responsible, what did cause the excess of miscarriages and birth defects during 1980 and 1981 in the Los Paseos area?

A. The observed excess may have been real and due to some unidentified cause.

On the other hand, the results may have been a result of selecting a study area in which an excess had already been suspected. This concept is difficult to understand. Perhaps the following example will help clarify the point. Suppose you happen to toss a coin many times. If you toss it long enough, by chance alone you will eventually see a long run of heads. Suppose an onlooker happens to notice this and says, "That coin just came up heads five times in a row. The odds of that happening by chance are very small, so I think you are using a weighted coin". Is this correct? To answer this question, you must observe the coin again by tossing it several additional times keeping track of the outcomes. Returning to the situation at Los Paseos, the original study confirmed the residents' suspicion that there was an excess, but this study was like going back and documenting that five heads had already occurred. Studying the new exposed tract is analogous to tossing the coin again several times.

Q4. Is there currently an excess of spontaneous abortions or birth defects in any of the areas studied?

A. No. We studied pregnancies through early 1985 and no excess of either miscarriages or birth defects was seen in any of the four areas studied.

Q5. Where are the four areas studied?

A. The boundaries of Los Paseos are the same as those of census tract 5120.12. These are Highway 101, Bernal Road, and the power line. The boundaries of the new exposed tract coincide with those of census tract 5120.11. This tract is bounded by Cottle Road, Bernal Road, Highway 101 and the power line. The control census tracts were 5120.08 in the City of San Jose and two smaller tracts combined (5053.02 and 5053.04) in the City of Santa Clara. We enclose a map showing the study areas.

Questions concerning the Cardiac Follow-up Study

Q6. Why was the Cardiac Follow-up Study conducted?

A. Severe cardiac defects were included among the birth defects reported by residents in the Los Paseos area. These defects occur infrequently (about 3 in 1000 live births) and the Pregnancy Outcome Study did not have enough births to determine whether an unusual number of these rare outcomes had occurred. In response to this concern, the Department conducted a second study in which hospital records throughout Santa Clara County for births in 1981 and 1982 were reviewed in order to look for cardiac defects. The 1985 Cardiac Study documented that there were two cases in Los Paseos, which is more than expected. We also examined defects among births to women living in the seven census tracts receiving water from the Great Oaks Water Company which operated the contaminated well. The Department found ten cardiac anomalies among women living in the seven census tract area when only four were expected. However, as was the case with the Pregnancy Outcome Study, no conclusion could be drawn regarding the role of the contaminated water in causing this excess of six cases.

This original study was based on hospital records and address at birth only and no interviews were conducted. Therefore, women who drank only bottled water, or women who moved to the seven-census-tract area shortly before they gave birth could have mistakenly been counted as exposed. Furthermore, we had very little data on pregnancies which began after the well was closed. Therefore, a decision was made to interview all cardiac cases born in 1981-83, as well as a random sample of normal live births, in order to study the time period after the well was closed, and to get more detailed information about exposure. This is the Cardiac Follow-up Study.

Q7. What did the Cardiac Follow-up Study find?

A. The interviews did not identify any unusual characteristics of women living in the Great Oaks area which could explain the excess. Obtaining more accurate information about water consumption, residence in the first trimester or place of work did not lessen the association. If anything, it strengthened it slightly. However, the distribution of birth dates of cases does not support the Fairchild leak as the cause. If the leak had caused the elevated number of cardiac anomalies seen in 1981 births, it should have caused a similar excess in the first nine months of 1982. This "cut-off" in September of 1982 is based on the fact that the contaminated well was closed on December 7, 1981, and because experts in the field believe that an infant's heart is most susceptible during the first seven weeks of prenatal life. Exposure to well water in November and the first part of December 1981 would have affected pregnancies ending in August and early September of 1982. If the same level of excess risk seen in 1981 had continued through the first nine months of 1982, seven cases would be expected in that time period. In fact, only two occurred. This difference is statistically significant, and makes the leak an unlikely cause of the 1981 cases.

On the other hand, using the hydrogeologic modelling described below, the cases exposed in 1981-82 did have a somewhat higher likelihood of exposure than the controls, so this piece of evidence would tend to support the leak as a causal factor.

Q8. Is there any evidence that water is related to cardiac defects in more recent births?

A. No. Based on the most recent data available (1983), the Department believes that water consumption is unrelated to these malformations anywhere within the county, and in the Great Oaks area in particular.

Q9. Are there any plans to study this problem further?

A. It will probably never be possible to determine conclusively what role the leak played in this observed cluster. However, the California Birth Defects Monitoring Program is conducting ongoing surveillance of these and other birth defects and investigates clusters related to water or other exposures when advisable.

Questions about the hydrogeologic modelling (Great Oaks Water Distribution Study)

Q10. Why was the Great Oaks Water Distribution Study conducted?

A. The 1985 Pregnancy Outcome Study made the assumption that all women residing in the Los Paseos area in 1980-81 were equally likely to have been exposed to the contaminated water from the Fairchild leak. This assumptions was made for simplicity, and because no other information was available. Two pieces of information were missing. The first concerns the timing and extent of the leak. When did it start and how rapidly did the concentration of chemicals increase in the contaminated well? This is a difficult question to answer because no water testing was done before the leak was discovered in December 1981. The second question concerns the distribution of the contaminated water to households served by the Great Oaks Water Company. Were they all equally likely to receive water from Well #13? Are there some areas which could be considered "unexposed"? The Water Distribution Study was conducted in an attempt to answer these questions.

Q11. How did the Water Distribution Study attempt to answer these questions?

A. The engineer who conducted this study, with the cooperation of the Great Oaks Water Company and various state agencies, collected a great deal of information about the water distribution system. He studied the network of 204 different pipes, pumping records for each well and records from meters to determine user demand in very small areas (nodes). Using sophisticated computer modelling he then estimated the proportion of water at each node which came from Well #13 for every month in 1981. Using these results, the Department then determined, for each pregnancy occurring in 1981, how much exposure to Well #13 water the woman received during the first three months of her pregnancy. This modelling was not done in 1980 because the engineer estimates that there was no appreciable exposure to this contamination in 1980.

What about the timing of the contamination? This question is more difficult. It was pursued in two ways. The engineer who modelled the water system estimated the timing of the initial leak under different assumptions, to get a range of estimates. An independent estimate was obtained by examining the material brought into and out of the Fairchild plant. This latter phase of the study is called the Materials Balance Analysis and is discussed in the next section.

Q12. What did the Water Distribution Study show?

A. The Water Distribution Study showed that the new "exposed" census tract (5120.11) was much more likely to receive water from Well #13 than the Los Paseos tract which was originally studied. In fact, for most of 1981, Los Paseos received less than 40% of its water from Well #13, compared to 80%-100% for most of 5120.11 during this time. The results on the timing of the leak are less certain, but none of the scenarios considered would predict that the contamination reached Well #13 in any appreciable amounts before January of 1981.

Q13. How do these results relate to the epidemiological studies?

A. With respect to timing of the leak: this report makes it appear unlikely that spontaneous abortions occuring in 1980 were related to the leak. Cardiac cases born in early 1981 are also less likely to be related to this exposure than those born later.

With respect to geography: these results document a higher likelihood of exposure to the contamination among the residents of 5120.11 (in which no elevated SAB rates were seen) than in Los Paseos (where the elevated rates were found). This makes it very unlikely that the elevation in Los Paseos was due to drinking water contamination from the leak. On the other hand, the modelling shows that, contrary to our prior assumption, contamination could have reached the cardiac cases born in the northwest portion of the seven-census-tract area served by the Great Oaks Water Company. In fact, estimates of exposure were somewhat higher for cases than for their controls in this study. This fact weighs somewhat in favor of Well #13 as a causal factor but the temporal distribution of cardiac cases weighs against it.

Q14. Could women have been exposed in any other way to this contamination, such as through air?

A. This water study cannot rule out the role of airborne contamination from the water, such as through vaporization. Furthermore, since a high percent of solvents are lost in industrial processes through evaporation, this route cannot be discounted. Unfortunately, available air monitoring data are very limited; there is a only one monitoring station in San Jose, for example. Therefore, it was not possible to do the kind of modelling for air that was done for water.

Questions about the Materials Balance Analysis

Q15. What is a Materials Balance Analysis and why was one done?

A. A materials balance analysis is commonly used in engineering studies to assess the inflow and outflow of materials through a system. The Fairchild analysis deals only with solvents which are considered by law to be hazardous materials and for which transport, storage and disposal records must be maintained. In this case, the balance equation is that material purchased should equal those used in processing, plus those hauled away. The difference between materials brought in and taken out or used in processing equals the amount lost, in this case in the Fairchild leak.

Following the discovery of the leak, the Fairchild company prepared a materials balance report at the request of the Regional Water Quality Control Board. The report indicated no appreciable leakage before late May 1980. The Department's analysis was conducted primarily to verify the reliability of this estimate.

Q16. What did the Materials Balance Analysis find?

A. The Department, with the cooperation of Fairchild and local agencies, reviewed a very large number of documents in an attempt to reconstruct the original report. Due to limitations in the available data and in resources to accomplish this task, the Department was only able to partially reconstruct the original analysis. Discrepancies were found, but no evidence to substantially alter the original estimates on the timing of the leak. Nevertheless, this analysis revealed considerable uncertainty in the data and the report concluded that there is insufficient evidence from which to draw firm conclusions about the exact mechanism or timing of the tank failure.

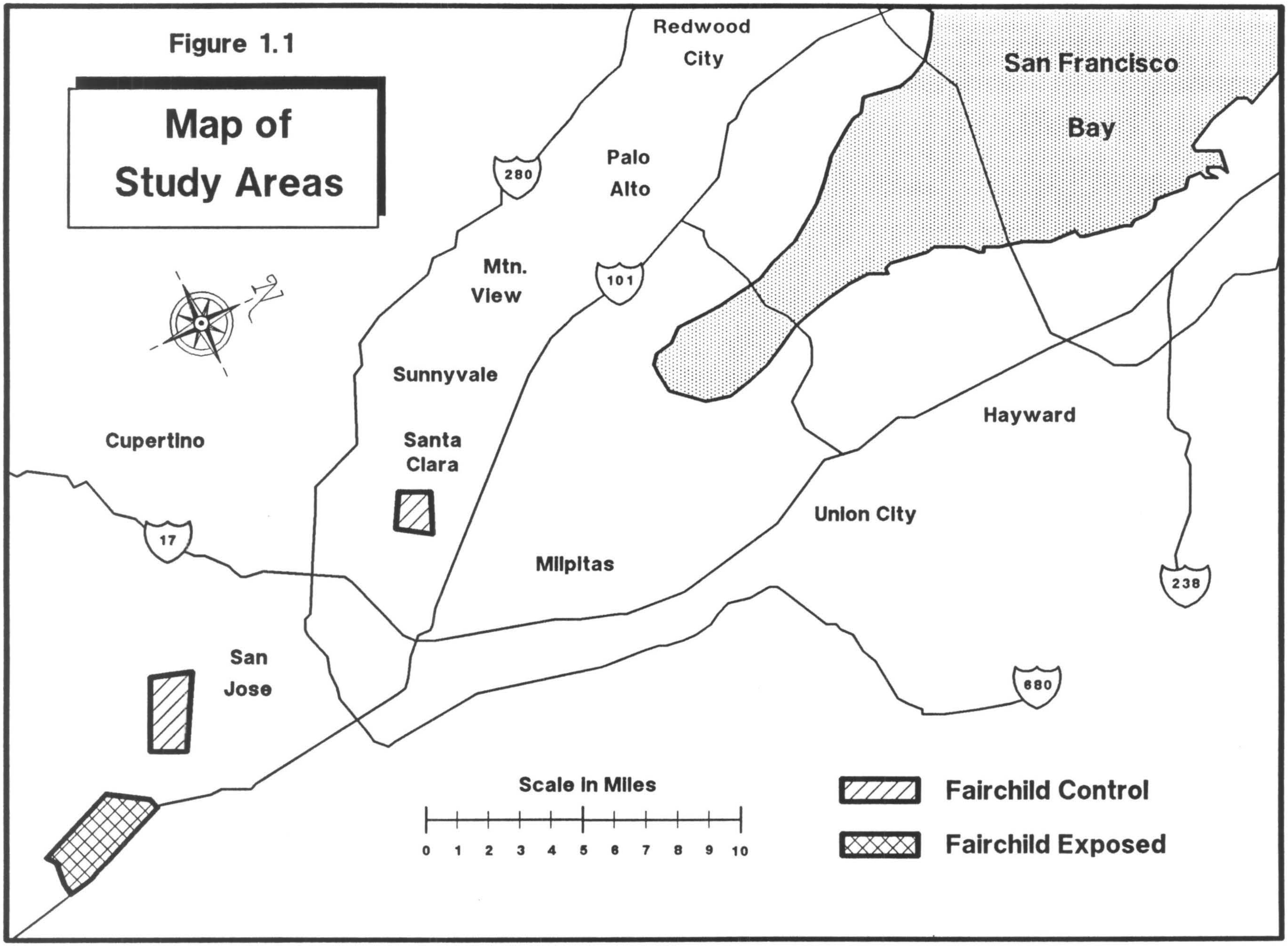


Figure 1.1

Map of Study Areas